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K001358

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI XFIX® DFS® Metaphyseal Correction System is provided as required per Section 513(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Jon Caparotta
Telephone: (973) 299-9022

Date prepared: April 27, 2000

2. **Proprietary Name:** EBI XFIX® DFS® Metaphyseal Correction System

Common Name: External Fixation Device

Classification Names: Single/Multiple Component Metallic Bone Fixation

Appliances and Accessories, 21 CFR 888.3030

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI XFIX® DFS® System – EBI, L.P.

4. **Description of the device:** The EBI XFIX® DFS® Metaphyseal Correction System has not changed the Indications for Use or fundamental scientific technology of the previously cleared system. The system consists of external fixation components and implantable bone screws. The EBI XFIX® DFS® Metaphyseal Correction System is utilized in the following manner: bone screws are inserted through the patient's skin and soft tissue and into the bone. The fixator frame of the EBI XFIX® DFS® Metaphyseal Correction System is

attached to the shanks of the bone screws. This submission is for additional components.

5. **Intended Use:** The EBI XFIX® DFS® Metaphyseal Correction System is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

6. **Materials:** The components of the System may be manufactured from materials such as titanium, stainless steel, and aluminum.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI XFIX® DFS® Metaphyseal Correction System and other currently marketed external fixation systems. It is substantially equivalent* to the predicate devices in regards to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Mr. Jon Caparotta
Manager, Regulatory Affairs
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054-1079

Re: K001358
Trade Name: EBI XFIX® DFS® Metaphyseal Correction System
Regulatory Class: II
Product Code: KTT
Dated: April 27, 2000
Received: April 28, 2000

Dear Mr. Caparotta:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K001358

Device Name: EBI XFIX® DFS® Metaphyseal Correction System

Indications For Use:

The EBI XFIX® DFS® Metaphyseal Correction System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001358